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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/126,559 07/30/98 CAPON

D 50130-E/JPW/

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HM22/0912

EXAMINER

BRUMBACK, B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

09/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/126,559</b>	Applicant(s) <b>Capon et al.</b>
	Examiner <b>Brenda Brumback</b>	Group Art Unit <b>1642</b>

Responsive to communication(s) filed on Jul 13, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1, 4, 8, 20, 25, 37, 40, 55-59, 62, 77, 91, 94, and 108-111 is/are pending in the application.

Of the above, claim(s) 20, 25, 59, 62, 77, 91, 94, and 108-111 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1, 4, 8, 37, 40, and 55-58 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

1. This action is responsive to the amendment filed 07/13/2000 (entered as Paper #10). Claims 1, 4, 8, 37, and 40 were amended. Pending claims are 1, 4, 8, 20, 25, 37, 40, 55-59, 62, 77, 91, 94, and 108-111. Claims 1, 4, 8, 37, 40, 55-58 are under examination.

2. This application contains claims 20, 25, 59, 62, 77, 91, 94, and 108-111 drawn to an invention nonelected with traverse in Paper No.8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

*Specification*

3. The objection to the specification for typographical errors is withdrawn pursuant to applicant's amendment thereof.

*Claim Rejections - 35 USC § 112*

4. The rejection of claims 4 and 40 under 35 U.S.C. 112, second paragraph, for recitation of genes encoding C, E1, E2, NS2, NS3, NS4, or NS5 is withdrawn subsequent to applicant's amendment thereof.

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5. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, for recitation of "IRES" and as depending from a canceled claim are also withdrawn subsequent to applicant's amendment.

6. The rejection of claims 1, 4, 8, 37, 40, and 55-58 under 35 U.S.C. 112, second paragraph, for indefiniteness of the preamble and for omitting essential steps is maintained. Applicant's arguments filed 07/13/2000 have been fully considered but they are not persuasive.

Applicant's argument that at page 40, lines 13-19, the disclosure teaches viral drug susceptibility as "the concentration of the antiviral agent at which a given percentage of indicator gene expression is inhibited" is noted; however, description of inhibition of an indicator gene does not in and of itself define what is being tested for susceptibility. Thus, the preamble of each of claims 1 and 37 remains indefinite. Amendment of the claims to indicate "susceptibility of an HCV viral segment to an HCV antiviral drug" would overcome this rejection.

Applicant argues that claims 1 and 37 recite measuring expression of the indicator gene in a target cell in the absence of an HCV drug. While the examiner agrees that claim 1 does recite "when steps (a)-(c) are carried out in the absence of the HCV anti-viral drug", it remains unclear what this measurement is being compared to, as the limitation of testing in the presence of antiviral drug is not recited until a later part of the claim. The syntax of the claim and the order in which the steps have been recited remains confusing.

Applicant's arguments regarding the teachings in the disclosure of determination of inhibitory concentrations based on comparisons of expression intensities of the indicator gene are

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noted; however these teachings do not satisfy the requirement for the presence of a correlation step in the claims. Although claims are interpreted in light of the specification, limitations from the disclosure are not read into the claims. Similarly, teachings found in the disclosure cannot be relied upon to fill in missing steps in a claimed method.

7. The rejection of claims 1, 4, 8, 37, 40 and 55-58 under 35 U.S.C. 112, first paragraph, is withdrawn. Applicant's arguments were persuasive.

*Claim Rejections - 35 USC § 103*

8. The rejection of claims 1, 4, 8, 55, and 57 under 35 U.S.C. 103(a) as being unpatentable over Gerna et al. in view of Lu et al. and Wang et al. and the rejection of claims 37, 40, 56, and 58 under 35 U.S.C. 103(a) as being unpatentable over Gerna et al. in view of Lu et al. and Wang et al. and further in view of Hirowatari et al. are withdrawn. Applicant's arguments were persuasive.

*Conclusion*

9. No claims are allowed.

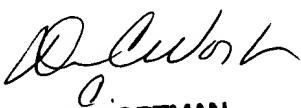
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback  
September 6, 2000

  
DONNA WORTMAN  
PRIMARY EXAMINER